Medacta International

JUL 18 2012

510(k) Summary

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Date Prepared: April 9, 2012

DEVICE INFORMATION

Trade/Proprietary Name: M.U.S.T. pedicle screw system
Common Name: Pedicle screw spinal system
Classification Name: orthosis, Spinal pedicle fixation, for degenerative disc disease

21 CFR 888.3070, 21 CFR 888.3060, 21 CFR 888.3050
Class III
Device Product Codes: MNI, MNH, NKB, KWQ, KWP

Predicate Devices:

K091445 CD Horizon, Medtronic
K042962 CD Horizon, Medtronic
K022949 USS, Synthes Spine
K100952 Matrix, Synthes Spine
K072022 Valeo, Amedica
K024096 Optima, U&I
K041119 Expedium, DePuy Spine
K083393 XIA 3, Stryker
K101074 Solera, Medtronic
K113174 Solera, Medtronic

Product Description

The M.U.S.T. pedicle screw system is intended to be used for the stabilization and the fusion of the lumbar and thoracic spine. The M.U.S.T. pedicle screw system is characterized by different sizes of screws and rods. The screws are fixed in the pedicle and the vertebrae. The rods act as a connector between the different screws to create a stable construct. The M.U.S.T. pedicle screw implants can be applied with the common surgical technique for posterior instrumentation.

The M.U.S.T. pedicle screw implants are made of Titanium alloy (Ti6Al4V ELI - ISO 5832-3, ASTM F136) and CoCrMo (ISO 5832-12, ASTM F 1537). The M.U.S.T. pedicle screw implants consist of either cannulated or non cannulated poly-axial pedicle screws. The screws are offered with a diameter between 4.5 and 7mm and a length between 20 and 90mm. The screw shaft is color anodized to simplify the identification of the screw diameter. The pedicle screw has a dual lead thread to simplify the screw insertion and reduce the number of turns. The threads are designed with a cylindrical diameter. The pedicle screw is connected by 5.5mm Titanium alloy (Ti6Al4V ELI - ISO 5832-3, ASTM F136) or CoCrMo (ISO 5832-12, ASTM F 1537) rods to create a stable construct. The rods are offered straight and pre bent. The pre bent rods have a curvature of 200mm. The construct is secured using a set screw made of CoCrMo (ISO 5832-12, ASTM F 1537). The pedicle screws, set screws and rods are available both in sterile and unsterile packaging.

Indications for Use

The M.U.S.T. pedicle screw system is intended for posterior non-cervical pedicle fixation (T1-S2/ilium) or anterolateral fixation (T8-L5). These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

Comparison to Predicate Devices

The M.U.S.T. pedicle screw system is substantially equivalent to the predicate devices in terms of intended use, material, sizes, and biomechanical performance.

Performance Testing

The M.U.S.T. pedicle screw system is substantially equivalent in mechanical performance to the predicates in regards to Static Torsion Yield Torque and Stiffness, Static Axial Compression and Dynamic Axial Compression Performance. The mechanical testing of the M.U.S.T. pedicle screw system included static and dynamic compression bending and static torsion according to ASTM F1717.

Conclusion:
Based on the above information, the M.U.S.T. pedicle screw system can be considered as substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Re: K121115
Trade/Device Name: M.U.S.T pedicle screw system
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, MNH, KWQ, KWP
Dated: June 22, 2012
Received: June 25, 2012

Dear Mr. Gross:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121115

Device Name: M.U.S.T. pedicle screw system

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Prescription Use ____x____ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121115